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Evaluation of Different Brands of Paracetamol Tablets

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Abstract:
Many brands of paracetamol tablets are available as over the counter product (OTC) in India which are widely used for analgesic and antipyretic effect. This study was conducted to compare and evaluate the different brands of paracetamol tablets available in the drug stores. Five different brands of paracetamol tablets were collected from various pharmacy shops and tested as per selected pharmacopeial and non-pharmacopoeial quality control tests. The parameters assessed includes the weight variation, friability, hardness, identification and disintegration time, The evaluation results indicate that all brands met the acceptable limits except for two brands that marginally failed the friability test. However, since friability is not considered as a Critical Quality Attribute in final product specifications, these tablets cannot be claimed as "failure to meet Quality Standards". Hence all brands ensure the safety and efficacy for consumer use at preliminary stage of evaluation. Further assessment, including critical quality control test should be conducted as part of the continuous assessment of the quality of marketed products.

Keywords: Paracetamol, Quality control test, market evaluation, brand comparison

1. INTRODUCTION

Quality control tests of tablets or evaluation of tablets is a systematic determination of physical, chemical, mechanical, biological, or microbiological properties of tablets on the basis of in-house (Non-Pharmacopoeial), Pharmacopoeial standards such as BP, USP, Ph. Eur., Ph. Int., JP, IP, ChP, or others guidelines such as ICH etc. To design the perfect tablets and later monitor tablet production quality, quality control tests of tablets or evaluation of tablets' physical, chemical, and bioavailability properties must essential. A variety of methods are used for the evaluation of tablets or conducting quality control tests of tablets. All of the quality control tests of tablets or evaluation tests of tablets are classified into three categories:

1.1 Pharmacopoeial tests

These tests follow regulatory guidelines such as USP, BP, and IP and assess various critical tablet parameters as described in Table 1. Identification tests confirm the presence of the active ingredient using techniques like HPLC and spectroscopy. Friability tests check the tablet's resistance to breaking during transit, while the disintegration test ensures tablets dissolve within the prescribed time in the body. Weight variation and uniformity of dosage unit tests verify that each tablet contains the correct drug amount. Dissolution testing, which measures the drug release rate, is crucial for determining bioavailability and bioequivalence. The assay test determines the actual drug content in a tablet, ensuring it falls within specified potency limits, while impurity tests check for unwanted substances that may form during manufacturing or storage.

1.2 Non-pharmacopoeial tests

These tests are determined by the manufacturer; include evaluating a tablet's appearance, thickness, diameter, hardness, and organoleptic properties such as color, odor, and taste. These factors influence patient compliance and identification while ensuring tablets maintain a consistent physical form. Hardness testing ensures tablets can withstand mechanical stress during handling and packaging, while thickness and diameter measurements help maintain uniformity for ease of administration and packaging compatibility.

1.3 Specific pharmacopoeial tests

These tests address additional quality parameters. Microbiological examination ensures nonsterile tablets do not exceed acceptable microbial contamination levels, which is particularly important for sugar-based and vitamin tablets. The acid-neutralizing capacity test applies to antacid tablets, measuring their effectiveness in neutralizing stomach acid. Splitting tests evaluate the accuracy of scored tablets to ensure proper dose division, while water content analysis determines moisture impact on tablet stability. These tests collectively ensure that tablets meet regulatory standards and provide safe and effective treatment for patients.

Table 1 : Different types of Quality control tests for tablets

Pharmacopoeial Tests of Tablets	Specific Pharmacopoeial Tests of Tablets	Non-Pharmacopoeial or In-House Tests of Tablet:
Identification Tests Friability Test Disintegration Test Weight Variation Test Uniformity of Dosage Unit Test Dissolution Test Assay Test Impurities Test	Microbiological Examination of Tablets Acid-Neutralizing Capacity Quality test of Splitting Tablets with Functional Scoring Water content	Appearance/ Description Thickness and Diameter Hardness Organoleptic properties

India's drug regulatory body, the Central Drugs Standard Control Organisation (CDSCO), has flagged around 50 drugs in May 2024, including popular medications like Paracetamol, Pantoprazole, and several antibiotics, for failing to meet quality standards. These substandard drug products can be a serious threat to the health care system and the public health.

This study was aimed to check, compare and evaluate the quality standards of commercially available Paracetamol tablets prescribed for fever and pain as over the counter drug product. Different brand of Paracetamol tablets (Dose 500 mg) were evaluated comparatively for the physicochemical quality using Pharmacopoeia and Non-Pharmacopoeia Test methods.

2. MATERIALS AND METHODS:

Sample Paracetamol Tablets, having label strength of 500mg of different brands were purchased from Medical Store.. All the study was performed within product expiration dates. The different brands were listed in table 2.

Table 2: List of the tested commercial Paracetamol Tablets

Brand Name	ManufacturingDate	Expiry Date	Pack size
Brand A	Oct-23	Sep-27	15's
Brand B	Jul-23	Jun-26	15's
Brand C	Jan-24	Dec-25	20's
Brand D	Mar-24	Feb-26	15's
Brand E	Mar-24	Feb-27	15's

The following tests were performed to evaluate the quality of the tablets;

2.1 Appearance/ Description

The appearance of a tablet is crucial for patient compliance and identification. The control of the appearance of a tablet includes the measurement of a number of attributes such as a tablet's shape, surface texture, diameter, thickness, color, absence or presence of an odor, taste, physical flaws and consistency, scoreline, and legibility of any unique identification markings such as embossed or engraved with a logo or letter(s).

2.2 Unique Identification Markings

Pharmaceutical companies often use some type of unique markings such as embossed or engraved with a symbol or letters or printing on the tablet for rapid identification. The tablets may score in halves or quadrants to facilitate breaking or to make the smaller dose. Intact and clear unique identification markings on tablets are acceptable.

2.3 Thickness of tablets

The thickness of the tablet is the only dimensional variable related to the tablet compression process. Generally, it is measured with a micrometer. The thickness should control within ±5% variation of a standard value and must control for patient acceptance and make the tablet packaging easier.

2.4 Diameter and Shape of Tablets

The diameter and shape of the tablets should control by the diameter and shape of the die and punches during the compression process. USFDA recommends that the diameter of the tablet should be 8 mm or less than 8 mm and should not exceed 22 mm. Generally, tablet shapes are round, oval, oblong, caplet, cylindrical, triangular etc. The upper and lower surfaces of tablets may be flat, round, concave, or convex to various degrees. The diameter and shape of the tablet influence esophageal transit, administration techniques (i.e., use of fluids, patient position), and irrespective of patient factors.

2.5 Organoleptic properties

Colour: Tablet colour is crucial for identification and patient acceptance.

2.6 Hardness of Tablets

Tablets require a definite amount of hardness to withstand mechanical shocks of handling in manufacture, packaging, and transportation without affecting the disintegration limit. Generally, oral tablets have a hardness of 4 to 10 kg. The units of measurement of tablet hardness was represented in Kilogram (kg)

2.7 Friability test of uncoated tablets

Friability testing is used to test the durability of tablets during transit (packing, transportation). Measurement of tablet friability supplements other physical strength measurements, such as tablet breaking force.

For ≤ 650 mg weight of tablets, take 6.5 g tablets or as near as possible to 6.5 g. For tablets with more than 650 mg weight, take 10 tablets. The tablets must be carefully dedusted prior to testing. Friability may calculate from the following equation:

$$\text{Friability (\%)} = \frac{\text{Initial Weight (W1)} - \text{Final Weight (W2)}}{\text{Initial Weight (W1)}} \times 100$$

Friability test limit: A maximum weight loss (obtained from a single test or from the mean of three tests) of not more than 1.0% is considered acceptable.

2.8 Disintegration Time Test

Disintegration is the process by which a solid oral dosage form such as a tablet breaks down into smaller particles or granules. The tablets must disintegrate and all particles must pass through the 10-mesh screen in the time specified. Complete disintegration is that state in which any residue of the unit (tablet or granules) except fragments of insoluble coating or capsule shell, remaining on the screen of the disintegration apparatus or adhering to the lower surface of the disk if used, is a soft mass having no palpably firm core. Disintegration is provided to determine whether tablets, capsules, or granules disintegrate within the prescribed time when placed in a suitable liquid medium in a 1000 ml beaker at 37°C

± 2°C. (Limit Not more than 15 minutes and if fail to comply repeat the test on a further 6 tablets, omitting the discs).

2.9 Uniformity of Weight (Mass) of Tablet

A weight variation test is performed to determine the consistency of formulated preparations. It is a pharmacopoeial test for the evaluation of tablets or quality control tests of tablets.

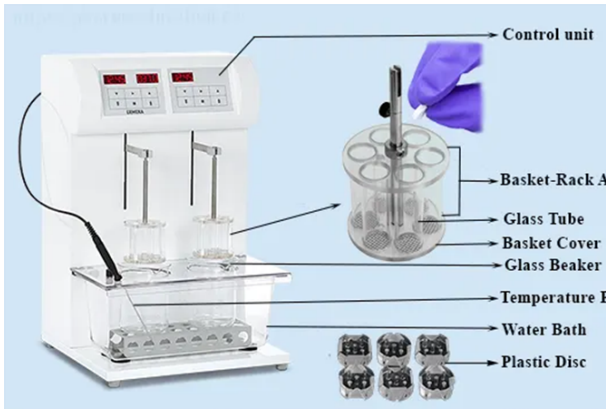

Figure 1: Disintegration time test apparatus

Table 3: According to USP, BP & IP the accepted limit of weight variation is given below:

IP/BP	Average Mass Limit	USP
Tablet weight 80 mg or less	± 10%	Tablet weight 130 mg or less
More than 80 mg or Less than 250mg	± 7.5%	130 mg to 324 mg
250 mg or more	± 5%	More than 324 mg

RESULTS

Table 4: Appearance of different Paracetamol Tablets

Brand Name	Appearance
Brand A	White, circular shaped, flat , scoring on one side, imprinted "BRAND NAME" on other side.
Brand B	White, circular shaped, flat , scoring on one side and plain on another side
Brand C	White, capsule shaped, biconvex, imprinted "BRAND NAME" on one side, advance on another side.
Brand D	White, circular shaped, imprinted "BRAND NAME" on one side.
Brand E	White, circular shaped ,scoring and imprinted "BRAND NAME" on one side and plain on another side

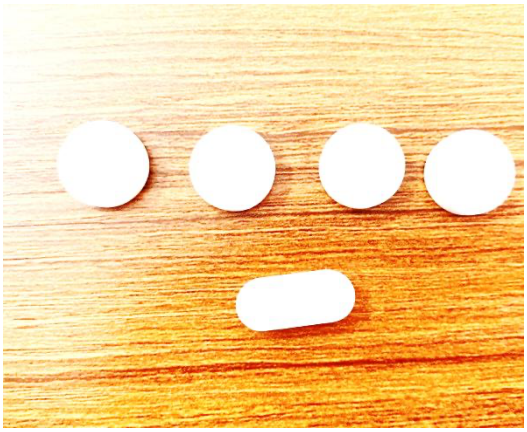

Figure 5 : Image of Different Brands of Paracetamol Uncoated Tablets

Table 5: Thickness of different Paracetamol Tablets

Brand Name	Thickness (mm)
Brand A	4.30 -4.50
Brand B	4.40-4.50
Brand C	3.75-3.80
Brand D	4.50-4.60
Brand E	4.60-4.80.

Table 6: Hardness of different Paracetamol Tablets

Brand Name	Hardness(kg.cm^2)
Brand A	11-12
Brand B	10-13
Brand C	9-10
Brand D	10-12
Brand E	12-14

Table 7: Friability test results of different Paracetamol Tablets

Brand Name	Friability %
Brand A	1.06*
Brand B	0.89
Brand C	1.10*
Brand D	0.89
Brand E	0.96

* Average of three tests were observed to be greater than 1%

Table 8: Disintegration time of different Paracetamol Tablets

Brand Name	Disintegration time (min.sec)
Brand A	1.27
Brand B	1.19
Brand C	1.05
Brand D	1.28
Brand E	1.29

Table 9: Uniformity of weight observed for different Paracetamol Tablets

Brand Name	Average weight of tablets (mg)	Percentage Deviation (%)
Brand A	596	-4.98 to + 2.68
Brand B	664	-2.11 to + 2.41
Brand C	660	-3.03 to + 3.00
Brand D	577	-3.99 to + 4.68
Brand E	610	-3.27 to + 3.28

CONCLUSION

Evaluation of five different brands of Paracetamol 500 mg uncoated tablets was performed using Pharmacopoeia and Non-Pharmacopoeia tests. The study revealed that all the brands conformed to the specifications for disintegration test and the uniformity of dosage units by weight. Two Brands (A & C) does not comply the friability test. Since friability test is not considered as Critical Quality Attribute (CQA) in Final product specifications, these tablets cannot be claimed as "failure to meet Quality Standards". Therefore, these products shall be further evaluated for critical quality tests like assay and dissolution in the future as part of the continuous assessment of the quality of marketed products.

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